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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

Some Labs Not Getting Paid for Molecular Assays; Result Is an Uncertain Future

Predictive Biosciences holds all the cards for a promising future—it's received more than $25 million in venture capital and its bladder cancer test is being distributed by ARUP Laboratories.

Yet despite having such tangibles in hand, Predictive's ever-more precarious fate rests on whether it will ever obtain money owed from the most reliable payer in health care history.

When the Centers for Medicare and Medicaid Services (CMS) announced late last year it was putting more than 100 new molecular pathology codes on the clinical laboratory fee schedule, it handed the duty of price-setting to its Medicare administrative contractors, or MACs.

Although the new payment rules went into effect on Jan. 1, the MACs had until April 1 to set draft prices. Most have yet to reveal their full prices, and CMS is not expected to announce all of them until April 30. That will be followed by a 60-day public comment period.

MACs that have released some pricing—Palmetto and Noridian—have been issuing revisions after coming under pressure from regional lobbies such as the California Clinical Laboratory Association.

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Labs, Pathologists Not Pleased EHR Safe Harbor May Be Extended

It's a safe harbor many in the laboratory and pathology sectors contend actually brims with mines.

This potentially explosive area with the seemingly benign name is the electronic health record (EHR) safe harbor exception to the Stark anti-kickback statute for physicians. It was put into effect in 2006, with the intent of allowing hospitals and other large providers to "donate" funds to physician practices in order for them to acquire EHR systems. So long as the practices put up 15 percent of the funding on their own, donations from other providers would, in many circumstances, avoid violating federal statutes prohibiting kickbacks.

The safe harbor provision had been set to expire at the end of this year, but earlier this month the Centers for Medicare and Medicaid

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Services and the Office of Inspector General of the Department of Health and Human Services proposed extending the protection through 2016. That's the last year the feds will be shelling out incentive payments to providers to achieve meaningful use for EHRs.

Clinical and anatomic pathology labs have been shelling out themselves—they are among those allowable donors under the provision. However, most labs are nowhere as deep-pocketed as the typical hospital. As a result, many say they have grown weary of making donations—particularly as some practices have unwittingly switched their referrals to more philanthropic competitors.

The College of American Pathologists has been critical of the safe harbor provision, claiming it leads to abuse, while the American Clinical Laboratory Association has maintained federal incentive payments to physicians to purchase EHR systems work better than the donations.

And such donations aren't just plinks into the passing plate: Ramping up an EHR system can cost a donor as much as $85,000, industry observers say. Donors can also be hit up for annual maintenance costs, which can run another $20,000.

"I'm trying to pay as little for it as humanly possible," said Krista Crews, the executive director at ProPath, a Dallas-area pathology and molecular lab. Crews estimated the 35-pathologist operation has been spending about $200,000 a year on donations. It's given to about 20 different practices over the past several years, Crews estimated.

And while the safe harbor provision seems likely to survive 2013, ProPath's donations are not. The recent 52 percent cut in the technical component of code 88305 has hit ProPath so hard that it has no budget for donations in 2014, according to Crews.

Smaller labs or pathology practices have never budgeted for it at all. Donations have been a nonstarter for Suncoast Pathology, a three-member practice and lab in Venice, Fla.

"It leaves us terribly stuck," said Richard E. Whisnant, M.D., one of the practice's members. Whisnant estimates that in 2010, Suncoast lost as much as 20 percent of its business to practices able to make donations. "We had been planning to survive until the end of 2013, and now it looks like this could continue."

Whisnant said that Suncoast will submit comments to CMS urging the end of the safe harbor provision. He also intends to talk to anyone in the media "who is willing to listen." "If the government wants to extend the safe harbor . . . they should police what to us appear to be illegal donations, so that it is a level playing field," Whisnant said.

However, not every physician practice is being wowed by new EHR systems—some have recently begun looking at their gifts in the mouth and found them wanting. Both ProPath and Suncoast say they have gotten back business from physicians who were less than thrilled with the EHR systems they received from donating labs. However, Whisnant observed that even after regaining the lost business, Suncoast is still more than 15 percent below where it was prior to the safe harbor provision being instituted.

As a result, ProPath has not endorsed any specific EHR systems, leaving the selection up to the practice. Crews noted that ProPath receives the invoices directly from the vendor, and pays them as well. "They seem much happier that way," Crews said.

Quest Reports Soft First Quarter, Says Numbers Will Improve in Second Half

Quest Diagnostics is trying to get past a series of disappointing earnings reports and reap the benefits of a reorganization recently orchestrated by Chief Executive Officer Steve Rusckowski.

However, as demonstrated by its first-quarter earnings report, it hasn't arrived there just yet.

Quest reported net income of $135.8 million, compared to $159.1 million for the first quarter of 2012, a drop of 15 percent. Revenue was $1.79 billion, compared to $1.9 billion for first quarter of 2012, a drop of 6.4 percent.

The company now forecasts that it expects to finish 2013 with revenues essentially flat, down slightly from prior guidance, when company officials expected it could have grown as much as 1 percent. Guidance regarding earnings per diluted share, projected to be about one-third higher than in 2012, remain unchanged.

"Our results for the quarter reflect our previously stated expectation for revenue softness during the first half of 2013, with gradual improvement throughout the remainder of the year," said Rusckowski. "Contributors to the first quarter's revenue softness include a challenging year-over-year comparison, continued weakness in health care utilization, and reductions in reimbursement driven by Medicare and commercial payers."

Rusckowski added that the company had continued to make progress in its reorganization, which eliminated more than 600 management positions, and in cutting costs. For the first quarter, operating costs and expenses were $1.55 billion, down about 4 percent from the prior year's quarter.

"While performance in the first quarter was adversely impacted by a number of factors, our efforts to restore growth, which are building momentum, coupled with easier year-over-year comparisons for the remainder of the year and the expectation of additional acquisitions, give us confidence in our full-year outlook for 2013," said Rusckowski.

Indeed, Quest announced a deal at virtually the same time it released its earnings report on April 17. The company announced it had acquired the lab outreach operations in California and Nevada of Dignity Health, a San Francisco-based not-for-profit hospital chain. It operates 35 hospitals in those two states, along with four others in Arizona.

The transaction is expected to close in June, pending regulatory approvals. Terms of the deal were not disclosed.

Inside The Lab Industry

PAML Plans Expansion of Direct-To-Consumer Testing

During the coming holiday season, consumers looking for a last-minute gift card on the checkout line might be able to decide if the recipient might prefer products from iTunes, Amazon, Applebee's, or PAML.

That's the ambition of one of the largest labs in the western United States. The Spokane-based PAML is launching a significant rebrand and expansion of its direct-to-consumer testing business that should be fully in place by the fourth quarter of this year, according to its chief executive officer, Francisco Velázquez, M.D.

One of the cornerstones of this strategy is gift cards that could be used to purchase a lab panel much in the same way consumers currently download songs or buy outdoor furniture online with relative ease.

PAML's reach for the direct-to-consumer business comes at a time when it remains a final, and often rugged, frontier for labs: chockablock with uncertainty, if not hostility, and haunted by the possibility of large losses.

The prospects scared off industry giant Quest Diagnostics, which refocused products it had marketed toward individuals to capture employer groups instead.

But Velázquez sees it differently. He noted that PAML's consumer sales are up 50 percent between 2008 and 2012, although it remains a tiny portion of the lab's overall revenues.

That appears to be in line with a gradual but consistent growth of the consumer testing market, which is known as direct-access testing or direct-to-consumer testing. Although it's still microscopic in volume when compared to the entire lab sector, data from G2 Intelligence suggest it's growing as much as 20 percent a year.

In PAML's case, the demographics have been telling: Most of the new users are women between the ages of 18 to 40 and males between the ages of 30 and 50. Indeed, PAML has engaged in such deep market research that Velázquez's observations on patient preferences seemed to have been lifted whole from a television programming or fast food chain exec's playbook.

"Those within the . . . 18 to 35 age group share vastly different preference patterns for [data] acquisition, and this type of consumer relies a lot more on the virtual world in order to do so," Velázquez said.

Add to that the ever-growing out-of-pocket costs for consumers. The average deductible for all health plans topped $1,000 a year in 2012, according to data from the Kaiser Family Foundation—nearly double what it was in 2006. And a third of those surveyed in a recent Kaiser tracking poll said they or a family

member had relied on over-the-counter products in the past year because going to the doctor is too costly.

Expanded Offerings

As a result, PAML has spiffed up the Web site for its consumer business, which is known as Results Direct™, and expanded its offerings. It currently offers more than 50 tests. Specimens are gathered at a local service center and sent in for testing. The tests range in price from less than $20 for a blood count screen to urinalysis for drug use to $175 for an adult food allergy panel. Gender-specific general health panels are $125.

Price List for PAML's Direct-To-Consumer Tests	
	Price
APO A or B	$85.00
BNP	$105.00
Comprehensive Cardiac Risk Panel	$175.00
Diabetes Screen	$25.00
hsCRP	$65.00
Occult Blood	$55.00
Thyroid Panel	$40.00
VIT-B1	$85.00
Women's Health Panel	$145.00
Source: PAML	

"As we see the higher out-of-pocket expenses, and we see more employers going into defined contributions, and people engaged in more health and well-being products, this seemed like the next logical step," Velázquez said. "We have comprehensive panels, basic metabolic profiles, and tests for cholesterol, iron, anemia. These are aimed at the type of traditional wellness factor that people want to monitor and follow up with."

He also noted that ordering tests directly from the laboratory tends to be less expensive than having them done at the doctor's office. "When you buy it off the shelf directly from a virtual environment, versus the doctor's visit, it tends to be somewhat more cost-effective," Velázquez said.

And while Velázquez is aware of the demographic breakdown of the users of such tests, he was careful to note the offerings are intended to have a multigenerational appeal. "Our goal is to really focus on the wellness and physiological components for patients," he said.

However, PAML does not intend to stop there. In addition to expanding Results Direct™, the gift card concept will be rolled out at traditional pharmacies and a large-box retailer Velázquez declined to name. And there is also a plan in the works to license a Food and Drug Administra-

tion-approved cell-gathering device patients can use to collect tissues at home and mail them directly to PAML for testing in a prepaid FedEx envelope that would come with the test. Results would be sent to patients electronically within seven to 10 days.

"If you survey consumers, the number-one reason for [marketing directly to consumers] is convenience, and it doesn't require traditional interface with other providers," Velázquez said. Pricing has yet to be set for that product.

Should test results occur outside the norm (such as a high cholesterol reading occurring within the testing), PAML's staff would notify the patient by phone and suggest they make an appointment with their physician.

Some Skepticism

Controversies about the direct-to-consumer market linger. Sean Valles, a professor at Michigan State University and a researcher of genetics, recently observed in the journal *Perspectives in Biology and Medicine* that "surprisingly little attention has been paid to the specific tests included in the panels offered by the various companies. Indeed, close examination of these tests demonstrates a pervasive problem in mail-order genomic testing: Ambivalence toward the goal of designing tests with clinical utility, or tests that medically benefit patients."

The College of American Pathologists has also suggested that vigilance be exercised in marketing tests directly to consumers.

"CAP believes that direct-to-consumer testing is clinical laboratory testing and should be subject to appropriate safeguards for health related conditions. While direct-to-consumer testing has the potential to empower patients in the management of their own health, it is no different than testing ordered by a licensed provider in that it poses a number of risks to the patient and public safety," John Scott, CAP's vice president of advocacy, said in a 2010 letter to the Oversight and Investigations Subcommittee of the U.S. House of Representatives.

And there is still some skepticism about the actual promise of the direct-to-consumer market.

"I don't see a great rush by labs to do this," said Jack Mattice of J.A. Mattice Associates, a laboratory consulting business based in Vancouver, Wash. Mattice also noted that some test positives—false or not—tend to trigger a stampede to the family physician. "Many docs consider it to be a nuisance," he observed.

But Velázquez noted that the prevalence of the Internet and smartphones means that younger patients are going to be driving a demand to monitor their health status on an ongoing basis. "We are providing for a niche that wants data right now," he said.

Mattice did say that he will be following how PAML's direct-to-consumer products fare.

"It will be interesting to watch," he said. G2

■ Some Labs Not Getting Paid, *from page 1*

Meantime, some labs are not getting paid for molecular testing performed on Medicare patients. Although many labs have a mix of business that has allowed them to weather the payment delays, it's put a company like Predictive in a bind, as about half of its revenue comes from performing molecular testing on Medicare enrollees. And it's become even more precarious since company officials projected Predictive would increase test volumes fivefold in 2013, reaching 40,000 by the end of the year. Predictive Chief Executive Officer Pierre Cassigneul said the unrealized Medicare revenues have totaled more than $2 million to date—an enormous amount for a startup company. It was getting paid about $400 a test under the old code-stacking price structure.

As a result, even though Predictive is in what Cassigneul termed a fast-growth mode, it has instituted a hiring freeze and has been trying to cut costs.

"We can't sustain this much longer," he said.

Also waiting on about $2 million in molecular-related Medicare payments is ProPath, a Dallas-area pathology and molecular lab. However, molecular is a relatively small part of its business and it can wait out the dry spell, said Krista Crews, ProPath's executive director. ProPath's MAC is Novitas, which recently took over from Trailblazer.

Although Predictive is based in Massachusetts, its laboratory is in Ohio. That state's MAC, CGS, has yet to release pricing for many molecular tests, including Predictive's bladder cancer test. A meeting with CGS officials in mid-April did not allay any of the company's fears.

"We are trying to resolve our situation with CGS but it is hard to understand where they stand and what they will do," Cassigneul said.

A CGS spokesperson did not respond to a request for comment.

The friction between the labs and the MACs was fairly evident at the recent American Clinical Laboratory Association annual conference. LabCorp Chief Executive Officer Dave King called on the MACs to be more willing to collaborate with the labs. But Marc Hartstein, director of CMS's hospital and ambulatory policy group, suggested that labs have not been forthcoming on their pricing information.

"The process has been difficult for all of us," he said.

In the meantime, Cassigneul said Predictive is looking for alternative forms of financing. With pricing in flux, neither banks nor factors—which lend against accounts receivable—will lend the company any money. So Predictive is going back to its venture capital investors—not to expand product lines, but to ensure they remain functioning.

"We're being strangled fairly rapidly, and it has to stop," Cassigneul said.

INDUSTRY BUZZ

Penn Medicine Launches Center for Personalized Diagnostics

The University of Pennsylvania Perelman School of Medicine's department of pathology and laboratory medicine has joined forces with its cancer center to create a new center for personalized diagnostics it expects will eventually service a significant part of the Philadelphia area.

The intent of the center is to improve the care of Penn's oncology patients by being able to develop targeted treatments based on specific genetic mutations of their cancers. One of the primary goals is to detect resistance mutations that could hamper response to targeted drugs and would therefore call for custom combination therapies—as well as identify patients who would have a poor prognosis undergoing standard therapies.

All new and relapsed patients being treated at Penn Medicine's Abramson Cancer Center are eventually expected to receive the genomic testing via blood tests and biopsies. Testing began earlier this year.

Currently, the center is focused on testing patients with blood cancers and solid tumors. It is testing for 33 genes for heme malignancies and 47 for solid tumors. The heme assay is a laboratory-developed test.

The center's typical turnaround for testing is two weeks—about half the average time for the region, officials said. The center has been focusing on MiSeq sequencing process, which is less labor-intensive than the HiSeq process, to obtain the results relatively quickly. Nearly 80 percent of patients whose cancers have been analyzed to date have had their prognosis or course of treatment altered as a result.

"This highlights the incredible clinical utility of utilizing multianalyte-based approaches to cancer diagnostics," said Robert Daber, Penn Medicine's technical director of clinical genomics.

Although the center remains relatively small, with two directors and five employees in total, it is slowly building momentum. It is currently testing between 30 and 40 patients a month, but that number is growing. By the summer, the center not only plans to expand the number of genes and abnormalities it will be testing, but it will also extend services to oncology patients outside of the Penn Medicine network. Officials said the reach of testing will also include pediatric patients.

References

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PAML
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Penn Center for Personalized Diagnostics
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Predictive Biosciences
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